

MARY ELIZABETH JENSEN, M.D.

Subject: Tommy Byrd Federal Report

Date: 2/19/21

I have been asked to provide a report of my opinions concerning my review of the record in the Tommy Byrd case. I have been asked to determine whether, after a review of the records and imaging, whether alternative interventions for Mr. Byrd would have changed his outcome. Please note that all of the opinions I have reached in this report are based upon my education, training and experience, and are to a reasonable degree of medical certainty.

PROFESSIONAL CREDENTIALS

I am a Professor of Radiology, Neurology and Neurological Surgery at the University of Virginia. I am board-certified in diagnostic radiology (1987). I completed a fellowship in Diagnostic Neuroradiology at the Medical College of Virginia (1987-1989) and a fellowship in Interventional Neuroradiology at the University of California at Los Angeles (1989-1990). Currently I practice both in a university medical center setting (University of Virginia Medical Center, Charlottesville, VA) and in not-for-profit private health systems, including Bon Secours Mercy (St. Mary's Hospital, Richmond, VA), Sentara Healthcare (Sentara Martha Jefferson Hospital, Charlottesville, VA), and Centra Health (Lynchburg General Hospital, Lynchburg, VA).

My practice includes providing care and treatment for patients with neurovascular lesions of the brain, spinal cord, and head and neck, including but not limited to patients with acute ischemic stroke due to thromboembolic disease, cerebral aneurysms, vascular malformations and other neurovascular lesions. The procedures that I perform are minimally invasive in nature, with the target lesion accessed either by endovascular or percutaneous routes. The details of my education, training, experience, and publications, are contained in my curriculum vitae, which is attached to this designation and incorporated.

As a member of several acute stroke intervention teams, I routinely diagnose and treat patients with large vessel occlusions using mechanical and/or suction thrombectomy

techniques. I have performed over 100 thrombectomies using a variety of devices, and I have taught these techniques in multiple didactic lectures, peer-reviewed and invited presentations, and in the angiosuite. I have participated in various stroke treatment trials, enrolled patients in stroke device trials, and have formally evaluated thrombectomy devices as part of the FDA Neurological Devices panel, which I currently chair. Since 2010, I have been the Society of Neurointerventional Surgery (SNIS) representative to the Brain Attack Coalition, a multi-subspecialty working group convened by the NIH's National Institute of Neurological Disorders and Stroke.

DOCUMENTS REVIEWED

I have reviewed the following documents:

- Medical Records of Mr. Tommy Byrd
- Radiological Imaging of Mr. Tommy Byrd
- Depositions of Dr. Jalabey (rough), Dr. Goracy (rough), and Dr. Yepes (final)
- Reports of Dr. Abhay Kumar
- Protocol for Nursing Management of a suspected ischemic stroke patient receiving recombinant t-PA therapy (2014)
- Management and Treatment of Acute Ischemic Stroke (2016)
- Protocol for Management of the Patient with Delirium (2015)
- Protocol for the Care of the Post-Surgical Patient (2016)
- VA Posters

FACTUAL BACKGROUND

On 11/15/16, Mr. Tommy Byrd, age 58 at the time, underwent a lumbar laminectomy with partial medial facetectomies and foraminotomies, at L2-L3, L3-L4, L4-L5.¹ A post-operative care note indicates that his anesthesia care ended at 4:54 pm that day.² At or shortly before 7:43 pm, Dr. Nicole McIntosh evaluated Mr. Byrd post-surgically.³ She noted that he was awake with minimal pain, normal temperature and with no apparent postanesthetic complications. She noted under disposition, "Patient has recovered from the immediate effects of anesthesia and may be transferred to ward or unit bed."

¹ Operative Note: USAO_BYRD_013274-78

² USAO_BYRD_012527

³ USAO_BYRD_012526-27

Sometime after this note, Mr. Byrd experienced acute confusion and agitation. Dr. Craig Jabaley, a staff physician, was passing through the ICU and found the patient confused and agitated. He testified that Mr. Byrd was having an acute change in mental status.⁴ Although he could not determine exactly when the change occurred, he testified that it happened either in the PACU or the ICU, which is consistent with the medical record documentation.⁵ After a brief exam, Dr. Jabaley concluded that Mr. Byrd was experiencing hyperactive delirium and notified the primary care team. Dr. Jabaley's description of the brief exam performed on Mr. Byrd can be found on pages 28-29 of his deposition.

Over the next few days, Mr. Byrd's delirium seems to subside. Events were documented as follows:

- 11/15/16 @1921 — A first year resident noted that he was alert and oriented to person but not place or time, and had to be reoriented.⁶
- 11/15/16 @ 0356 — continued agitation, tachycardia, hypertension as well as restlessness.⁷
- 11/16/16 @ 0753 — Orthopedic surgery examined Mr. Byrd and notes that he was restless post-operatively until 3 AM; psychiatry has been consulted but no acute events overnight. The note stated that bilateral lower extremities had increased sensation. He was sleepy but following commands.⁸
- 11/16/16 @ 0809 — A mental health consultation concluded, "58M with unknown psych history consulted for hyperactive delirium in the context of recent surgery and anesthesia, ICU stay, and a missed dose of several medications."
- 11/17/16 @ 0822 — He is oriented to person and place but still restless. He indicated a pain level of 3/10. His mental status is noted by the nursing staff as "oriented to own ability/knows own limitations."⁹
- 11/17/16 @ 0843 — Orthopedic surgery noted that he is oriented and in

⁴ Dr. Jabaley Deposition, pg. 40

⁵ Dr. Jabaley Deposition, pg. 28-29

⁶ USAO_BYRD_012525

⁷ USAO_BYRD_012523

⁸ USAO_BYRD_012502

⁹ USAO_BYRD_012476

excellent spirits, and ready to go home with well controlled pain. No acute events overnight.¹⁰

- 11/17/16 @ 0915 — A social worker note indicated that the patient was oriented x4 with logical and goal oriented thought process. While discussing reports regarding veteran's behavior after surgery, the veteran responded that he does not remember any of that.¹¹
- 11/17/16 @ 2015 — Patient wake in bed alert and oriented x3.¹² (throughout this time period he seemed to have fluctuating pain levels, as expected from surgery and the timing of pain medication administration).
- 11/18/16 @ 0830 — Nursing notes stated patient is alert and oriented to person and place but restless.¹³
- 11/18/16 @1110 — Orthopedic surgery resident's note stated Mr. Byrd is resting comfortably but is not cooperating or following commands, although under the PE portion of the note, Dr. Patel documented "NAD [no apparent distress], sleepy, following commands." His mental status is unclear based upon this note.¹⁴
- 11/19/16 @ 1132 — Orthopedic surgery noted that the patient is feeling much better today, sitting up in chair. Says he wants to go home but still has not cleared PT. Per Nursing, very unsteady, psychologically labile, and tachycardic.¹⁵
- 11/19/16 @ 2248 — Mr. Byrd reported that he is feeling better but he hurts when he moves. The nurses noted that he is awake, alert and oriented x3.¹⁶
- 11/20/16 @ 0742 — nurses noted that Mr. Byrd is out of bed and moving without complaints. "Remains alert and oriented x3, with intermittent confusion and agitation. Resting comfortable without s/s distress".¹⁷

On 11/21/16 @ 0720, Dr. Patel, the orthopedic surgery resident saw Mr. Byrd and noted that they were expecting to discharge the patient. Subjectively, "patient doing well and

¹⁰ USAO_BYRD_012473

¹¹ USAO_BYRD_012472

¹² USAO_BYRD_012465

¹³ USAO_BYRD_012462

¹⁴ USAO_BYRD_012460

¹⁵ USAO_BYRD_012451

¹⁶ USAO_BYRD_012448

¹⁷ USAO_BYRD_012450

wants to go home".¹⁸ Under "A/P", the note stated "need SAR. DC to SAR on Monday. Must stay in ICU for 1:1 monitoring and tele." On 11/22/16 @ 0800, Mr. Byrd cooperated with a nursing exam, but indicated that he wants to go home "I'm tired of being here." Physical therapy cleared him for discharge home that morning at 10:40am.¹⁹ On 11/22/16 @ 1048, a note by Daniel Minkow, OT showed that Mr. Byrd successfully completed an occupational therapy session with no abnormal behaviors noted.²⁰

On 11/22/16 @ 1102, Holly Lightkep, MSN, entered a note describing the events of a Code 44 called on Mr. Byrd by providers. Whereas just minutes before Mr. Byrd had completed an OT session, he suddenly became confused, was unable to say why he was hospitalized, was disoriented to time, unable to say the year, and answered "I have no idea." Mr. Byrd was given IM Haldol, and a psychiatry consultation was requested.²¹

According to the chart, Frederick Boyer, DO, a Psychiatry Fellow saw Mr. Byrd @1245.²² Dr. Boyer noted that Mr. Byrd was alert and oriented x3 until a sudden change, where a code 44 had to be called. The fellow observed Mr. Byrd was sitting up in bed looking around in a confused manner. He was slurring his speech, which was also confirmed as seen by Dr. Goracy in deposition.²³ He was unable to follow commands. Under cognitive exam, the following was documented:

A&Ox0, unable to detail person "Pool dog train is bag going to", place "I'm people ton", situation "know the human" or date "human". Reflexively reaches for examiner's hands when held out to patient, however, unable to follow any verbal commands, such as unable to stick out tongue, lift feet from bed, or take folded paper from this writer's hand.

The assessment documented that this mental status change was an acute change from A&Ox3 to A&Ox0. In the assessment, Dr. Boyer noted "we do not feel that the patient's altered mental state is volitional."²⁴ In the plan, Dr. Boyer stated "could consider neurological evaluation given teams report of sudden acute mental status change from A&Ox3." Dr. Goracy testified to this acute change in mental status in her deposition (pg. 94), and that there was an underlying pathology causing Mr. Byrd's presentation (pg.

¹⁸ USAO_BYRD_012437. At page 12431, discharge instructions were entered into his chart.

¹⁹ USAO_BYRD_012423

²⁰ USAO_BYRD_012421-22

²¹ USAO_BYRD_012419

²² USAO_BYRD_012405-10

²³ USAO_BYRD_012407-8, Dr. Goracy Deposition, pg. 97.

²⁴ USAO_BYRD_012408

96-97).

William Schultz, M.D., a second years medicine resident on the neurology service saw Mr. Byrd on 11/22/16 @ 1623 for a chief complaint of “encephalopathy.” William Schultz, M.D., a 2nd year medicine resident noted the staff report of Mr. Byrd’s acute mental status change from AAOx3 to AAOx0.²⁵ His exam showed “the patient is awake and talking but not responding appropriately.” On the patient’s mental status exam, Dr. Schultz reported “awake, alert, oriented x 0, no aphasia, no dysarthria. Follows commands intermittently, Mimics actions.” However, the examination does not note the slurred speech or language difficulties that Dr. Goracy and her resident observed and testified to in deposition (pg. 91). The resident concludes that there’s “no focal deficit to suggest CVA and no evidence or risk factors for seizure activity.”²⁶ Despite the findings of an acute mental status change in a patient who does not speak, follow some commands and pantomimes the examiners movements--all behaviors that had not been reported before and were sudden in onset--an acute ischemic stroke was ruled out because the patient had “no focal deficit.” Evaluation of the brain and its feeding vessels with non-invasive neuroimaging was not ordered.

Mr. Byrd continued experiencing similar symptomatology until another neurology consult on 11/23/16 @ 1431 was done.²⁷ In this exam, also done by Dr. Schultz, Mr. Byrd is alert and oriented x1, but it is noted that he has anomia aphasia, with the conclusion that the “patient has speech deficits that are concerning in the setting of otherwise being alert and awake.”²⁸ An MRI was recommended, but one was not performed until the next day.

On 11/25/16, a non-contrast brain MRI and an MRA of the head were performed.²⁹ It revealed infarction, i.e. stroke, involving the left temporal lobe and a portion of the left parietal lobe cortex and subcortex. The impression was an “acute to early subacute subtotal left MCA infarct affecting the territory associated with the inferior division branch. This is a large vessel stroke in the posterior MCA with proximal M2 cutoff.”

On 11/28/16, a carotid doppler was performed on Mr. Byrd.³⁰ There was scattered fibrocalcific plaque in the distal common carotid artery and extending into the internal

²⁵ USAO_BYRD_012403

²⁶ USAO_BYRD_012404-5

²⁷ USAO_BYRD_012382-84

²⁸ USAO_BYRD_012383-84

²⁹ USAO_BYRD_011566-69

³⁰ USAO_BYRD_011565-66

carotid artery. The velocities within the left carotid artery bifurcation were consistent with a moderate stenosis of 50-69%. No hemodynamically significant stenosis involving the right ICA was found. Mr. Byrd had a transthoracic echocardiogram (TTE) which was negative for intracardiac thrombus, valve vegetations or left to right shunting. He was also monitored on cardiac telemetry during his hospitalization which showed multiple episodes of sinus tachycardia but no episodes of atrial fibrillation. After reviewing the carotid doppler, the TTE and the telemetry, neurology concluded:

"58 y/o man with acute change in mentation found to have a left posterior MCA stroke with proximal M2 cutoff. This fits with his receptive > expressive aphasia. Mechanism is cryptogenic at this point although suspect cardioembolic".³¹

OPINIONS

I reviewed the MR imaging (MRI) and MR angiogram (MRA) performed on Mr. Byrd on 11/25/16. The imaging study was started at 1:00 pm and completed at 1:21 pm. The diffusion weighted study (DWI) shows restricted diffusion involving the left insular cortex, the superior portion of the left temporal lobe, and middle and posterior portions of the left parietal lobe. The apparent diffusion coefficient (ADC) map shows corresponding hypointensity in the same territory. The T2-fluid-attenuated, inversion recovery (FLAIR) sequence shows hyperintensity involving these same regions, as do the T2-weighted images. The T1-weighted images show matching hypointensity in the infarcted areas. The infarct involves Wernicke's speech area, which is necessary for comprehension of spoken and written language. Patients with strokes in this area have a sensory aphasia, and will often speak nonsensically ("word salad"). They are capable of stringing words together but they lack meaning ("fluent aphasia"). Mr. Byrd also demonstrated "pantomiming" by his attempt to mirror the examiner's movements. Damage to the dominant parietal cortex, such as Mr. Byrd's, will result in "pantomiming."

The MRA shows abrupt cut-off of the left MCA inferior division just distal to the MCA bifurcation. This division supplies the territories that are infarcted, and the location of the cut-off, which is most likely due to an embolus, would be amenable to mechanical thrombectomy.

I have reviewed the reports of Dr. Abhay Kumar, who believes the standard of care was breached when the providers failed to recognize the signs and symptoms of stroke. As I

³¹ USAO_BYRD_012275

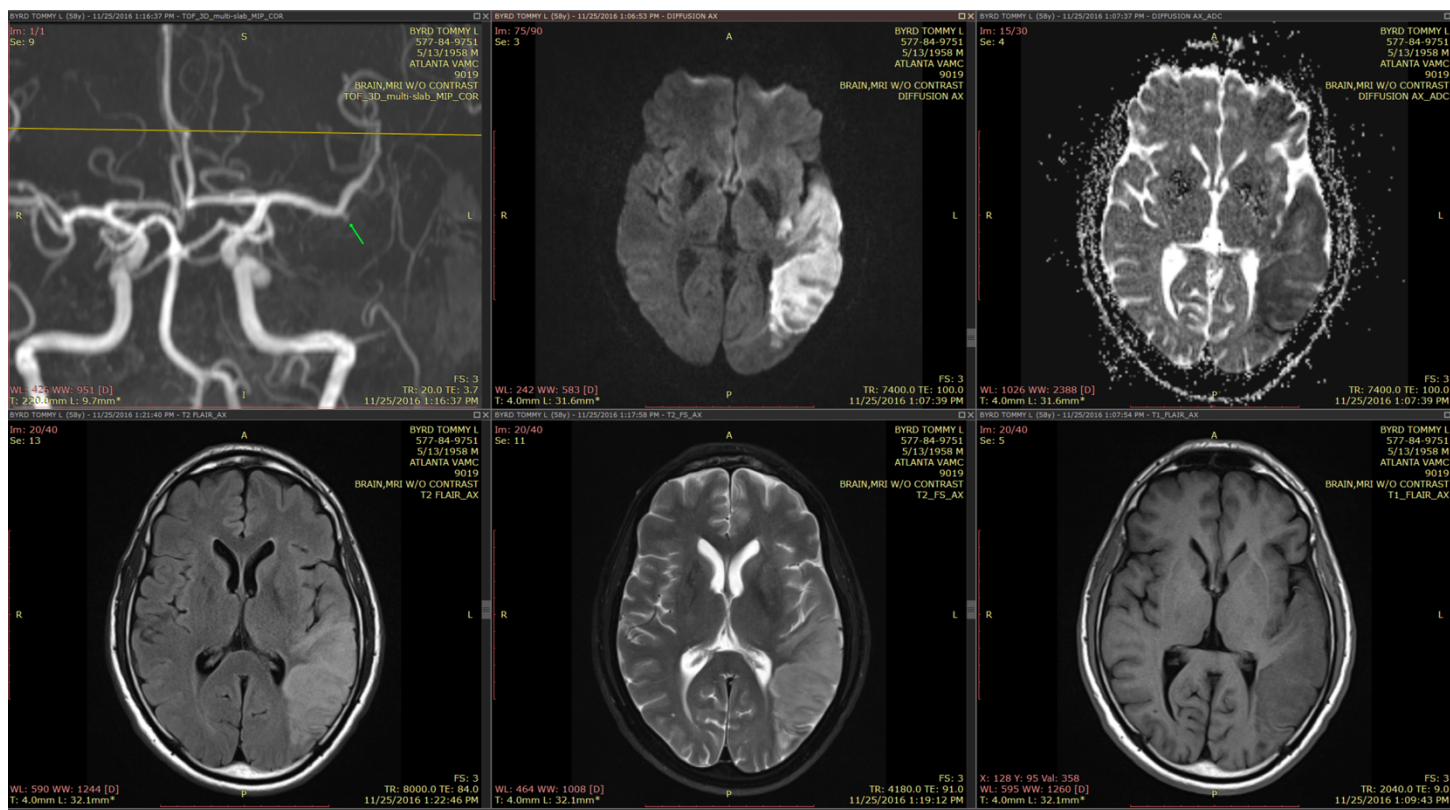
understand from his report, he opines that Mr. Byrd suffered an initial clot, which dissolved over time, corresponding to Mr. Byrd's decrease in agitation between Nov. 15 and Nov. 22. Then, sometime after 11:00 am on Nov. 22, 2016, Mr. Byrd experienced a second stroke event.

From reviewing the deposition testimony, the VA providers believed that Mr. Byrd's initial presentation between Nov. 15-22 was not stroke related.³² However, Dr. Yepes (staff neurologist for the VA) testified that based on his review of the imaging from Nov. 25, 2016, the stroke occurred seven to ten days prior to the MR imaging.³³ Therefore, according to Dr. Yepes timeline, Mr. Byrd's stroke occurred sometime between Nov 15th and Nov 18th.

I disagree with Dr. Yepes' interpretation of the MRI findings as they relate to the timing of the stroke. Acute infarction is detected first on DWI/ADC maps in the hyperacute phase, followed by its presence on FLAIR, T2-WI and T1-WI, respectively, in the acute and subacute phases. On this study, the infarcted areas are present on the DWI, ADC, FLAIR, T2-WI and T1-WI sequences, meaning that the infarct is at least 16 hours old. However, the DWI images show significant hyperintensity (bright on imaging), whereas, the ADC map is not similarly significantly hypodense (dark on imaging) in its appearance when compared to the DWI. This finding is important, in that the ADC map goes through a "pseudo-normalization" phase, where it gradually becomes less conspicuous (less dark) over the first seven to ten days, while the DWI findings remain hyperintense (bright). In Mr. Byrd's MRI the "darkness" of the infarct on the ADC map is easily seen, although not as much as the DWI "brightness." If this infarct were seven to ten days old as Dr. Yepes' opines, then the ADC map would show minimal or no findings of infarction. However, since it is present but less conspicuous than the DWI, the infarct is most likely three to four days old. This corresponds with the acute change in mental status on Nov. 22, 2016.

³² Dr. Jabaley Deposition, pg. 27-38.

³³ Dr. Yepes Deposition, pg. 71-73.



It is my understanding from reviewing the policies and procedures of the VA hospital that, in 2016, it had the ability to provide t-PA therapy to its patients. Mr. Byrd may not have been a candidate for IV tPA because his surgery was within the last 14 days, and recent surgery is a known contraindication for the use of IV tPA. However, in some instances, surgeons will agree to administration of t-PA in circumstances where a potential hematoma could be monitored and/or surgically removed.

Even if it was determined that t-PA was contraindicated, the hospital had a protocol in place for the Management and Treatment of Acute Ischemic Stroke that would have allowed Mr. Byrd to be a candidate for mechanical thrombectomy. In 2016, the time window for treatment of an acute stroke with mechanical thrombectomy was in the first eight hours of onset of symptoms. Ideally, the procedure should be started within six hours of "last known well," but it had to end by the eighth hour. As time is of the essence to meet this tight deadline, patients with acute ischemic stroke need to be identified quickly so the treatment timeline can be met.

At the time of Mr. Byrd's hospitalization, it was hospital policy that in-patients with

"symptoms or signs consistent with AIS must be evaluated within 10 minutes by the corresponding physician (hospitalist and/or Inpatient Medical Team) followed by the activation of the Acute Stroke Team."³⁴ For both in-patient and ED units, the treating provider is responsible for documenting in the record the time of the onset of the symptoms, when the patient was last observed not having neurologic symptoms, when the patient was first seen by the nurse or staff, when the patient was first seen by an MD, the time when the acute team was activated, and the time when the acute stroke team responded.³⁵

Mr. Byrd clearly had a sudden neurological event on Nov. 22, 2016 at approximately 11:00 am that was documented in the medical record. I understand that the Atlanta VAMC had the ability to transfer patients who needed mechanical thrombectomy to either Emory University, which is in close approximation to the VA hospital, or to Grady Hospital located approximately 8 miles away.³⁶

"TIME IS BRAIN"

For the purposes of this report, I am not opining on the standard of care at the hospital. However, assuming that the providers had taken prompt action on November 22, 2016 (e.g., emergent activation of the stroke team, immediate imaging, institution of stroke protocols, etc.) as discussed by Dr. Kumar, I believe that, more likely than not, Mr. Byrd would have been transferred to a local facility for mechanical thrombectomy. The clock started ticking on Nov 22nd at 11:00 am, when Mr. Byrd was noted to go from A&Ox3 to A&Ox0, with a sudden, new aphasia and slurred speech. To a reasonable degree of medical certainty, Mr. Byrd's best hope to preserve his left temporal and parietal lobe function was lost when the acute stroke intervention team was not activated, and by the time the embolus was discovered on an MRA three days later, his brain was irreversibly damaged by an embolus that could have been removed endovascularly. Because Mr. Byrd was hospitalized, he was in the best position possible to have his stroke deficits addressed immediately. But because Mr. Byrd's stroke was not timely addressed, to a reasonable degree of medical certainty, Mr. Byrd lost precious time, which would have been used to minimize or eliminate his deficits.

Mr. Byrd had an embolus that should have been discovered and treated on 11/22/16.

³⁴ USAO_BYRD_011259

³⁵ USAO_BYRD_011259

³⁶ Dr. Yepes Deposition, pg. 25-26.

Leaving his left MCA inferior division blocked for as long as the providers did prevented Mr. Byrd from being within the narrow time window for appropriate medical and endovascular management from the stroke team, including getting appropriate vascular imaging (CTA), perfusion studies (CTP), mechanical thrombectomy (MT) and acute management of brain swelling that help prevent permanent brain damage. The longer an embolus obstructs a brain blood vessel, the more likely the brain tissue it supplies will die, and the more likely the patient will lose neurological function that is permanent. Mr. Byrd is evidence of this principle. In my experience, given the location of the embolus and the status of Mr. Byrd's left carotid circulation (minimal atherosclerotic disease and no tortuosity), the embolus obstructing the MCA inferior division could have been easily accessed and extracted. I believe that timely intervention would have minimized or eliminated Mr. Byrd's deficits.

I reserve the right to expand upon this report if I am asked new questions in testimony. Please do not hesitate to contact me if you have further questions concerning this report.

Signed: /s/ Mary Elizabeth Jensen, M.D. _____

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